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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,209	12/18/2000	Jaan Noolandi	D/A0489	4337

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EXAMINER

DAWSON, GLENN K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/740,209

Applicant(s)

NOOLANDI ET AL.

Examiner

Glenn K Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-17, 19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-17, 19 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12-20-2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-7,9-17,19 and 21-24 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

U.S. Patent No. 6622720 having a different inventive entity discloses the exact same invention as that claimed in the present application. It is therefore unclear exactly who invented the claimed subject matter recited in the pending claims of the present application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boucher, et al.

Boucher discloses a driver generating acoustic energy to form capillary waves for emitting droplets of pharmaceutical product. However there is no actual disclosure of the droplet being inhaled. Since the entire disclosure is drawn to the atomization of inhalants, it would have been obvious to have manufactured the droplets and then used them by providing them to a patient in need of inhalation therapy

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Claims 1,2,5,6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elrod-4748461 in view of either Elrod, et al.-4751530 or Oeftering-5722479.

Elrod discloses a system having a driver generating acoustic energy which forms capillary waves on the surface of a pool of ink. Known means are employed for focusing the energy to cause the capillary waves. However, the acoustic lens is not disclosed. Both Elrod and Oeftering disclose that it was known in the art of ink printing to focus the acoustic energy of a droplet emitter with an acoustic lens. It would have been obvious to have used an acoustic lens to focus the energy of Elrod, as Elrod stated that any focusing means could be used and as evidenced above, acoustic lenses were known for this exact purpose.

Claims 3,11,14,15,19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elrod-4748461 in view of either Elrod, et al.-4751530 or Oeftering-5722479 as applied to the claims above, and further in view of Roy-6302524.

Elrod as modified above makes obvious the invention as claimed with the exception of the type of lens, the delivery system of a pharmaceutical product and the distance from the lens to the reservoir. Roy discloses that fresnel acoustic lenses were known. To have used a fresnel acoustic lens for the acoustic lens disclosed by Elrod or Oeftering would have been obvious as these types of lenses have found use in droplet emitters. Roy also discloses that the pressure of the fluid being formed into droplets needs to be regulated for proper droplet formation. It would have been obvious to have provided the system of Elrod with a delivery system which kept the fluid under pressure

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and in the proper location, as taught by Roy, as this allows for proper droplet formation. It was notoriously well known in the art to place the lens at a distance of the focus of the lens to achieve proper droplet formation. Therefore, to have used a lens having the claimed focal length would have been an obvious design choice as the distance needs to be very small and the exact distance could be tailored to the specific lens. Roy also teaches that the principles of AIP are suitable for the ejection of biological compounds and therefore, it would have been obvious to have used the device to form droplets of a pharmaceutical product as it was known to use droplet emitters to form inhalable droplets.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Elrod-4748461 in view of either Elrod, et al.-4751530 or Oeftering-5722479 as applied to the claims above, and further in view of Roy-6302524 as applied to the claims above, and further in view of Hakkinen-5063922.

Elrod as modified above makes obvious the invention as claimed with the exception of the detection circuit. Hakkinen discloses that it was known to provide ultrasonic atomizers with an inhalation detection circuit. It would have been obvious to have provided Elrod's device with an inhalation detection circuit, as taught by Hakkinen, as this allows for the power of the droplet emitter to only be delivered when the medication is ready to be inhaled thus minimizing possible losses of product.

Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elrod-4748461 in view of either Elrod, et al.-4751530 or Oeftering-5722479 as applied to the claims above, and further in view of Hirahara, et al.-6045208.

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Elrod makes obvious the invention as claimed with the exception of the lens being plastic. Hirahara discloses that plastic fresnel lenses were known. It would have been obvious to have manufactured the acoustic lenses of the above combination out of plastic, as such materials are easily molded or formed into the proper shape.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-17 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6622720. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader in scope than those dependent claims, such as claims 8-10 of the patent.

Response to Arguments

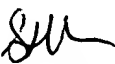
Applicant's arguments with respect to the rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Glenn K Dawson
Primary Examiner
Art Unit 3731

Gkd
16 March 2005